

REMARKS

I. Status of Claims

1. Claims 1-123 remain pending in the application.
2. Claims 1-94 and 97-116 are cancelled without prejudice or waiver by this Amendment. Applicants reserve their right to file a divisional application(s) on the cancelled claims.
3. Claims 95, 96 and 117-123 have been amended by this Amendment.
4. As a result of the present Amendment claims 95, 96 and 117-123 remain under examination in this application.

II. Rejection under 35 USC §101

5. Claims 95, 96, 117-113 were rejected under 35 USC §101 on the basis that the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record. The Examiner has specifically noted that the only point of disagreement appears to be in the interpretation of what constitutes a specific, substantial, and credible utility. The Examiner has again premised this argument on the holding of *Brenner v. Mason*, 148 USPQ 689 (S. Ct. 1966). Applicants respectfully traverse this rejection.

It is respectfully submitted that the utility analysis of the claimed chemical moiety of *Brenner v. Mason*, cited above, is not analogous to the utility examination of the present antibody claims. It is noted that the *Brenner v. Mason* decision was handed down in 1966, some nine years prior to the work of Kohler and Milstein on monoclonal antibodies, see Kohler, G. and Milstein, C., *Nature*, (1975) 256 (5517):495-497 (Copy provided as Exhibit A). It is also noted that the case law specific to antibodies has been further clarified by the Court of Appeals for the Federal Circuit in a decision during the pendency of the present application. The holding of *Noelle v. Lederman*, 69 USPQ 2nd 1058, 1514 (CA FC 2004) (Copy provided as Exhibit B) is directly and factually analogous to the pending antibody claims of the present application. The Court in its decision was quite specific, stating that

“Therefore, based on our past precedent, as long as an applicant has disclosed a ‘fully characterized antigen’ either by its structure, formula, chemical name, or physical properties, or by depositing

the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.”

This is exactly what Applicants have taught in the present application. Further, Applicants have specifically identified the antigen as being a human ion channel. Applicants’ specification as detailed in earlier responses has noted the utility of the claimed antibody in both therapeutic and diagnostic applications. Applicants respectfully submit that in view of the decision of *Noelle v. Lederman*, and the teaching of Applicants’ specification, the utility requirement under 35 USC §101 has been properly met.

Applicants reiterate their previously filed arguments that the utility requirement for the present claims has been met by the teachings in the specification. Further, in Applicants’ response mailed October 14, 2004, Applicants provided as Exhibit A the paper of Niesler, B. et al. *Gene* (2003) 310: 101-111 which confirms the identity and utility of the ion channel of the present invention.

Applicants submit that when a properly claimed invention meets at least one stated objective, utility under §101 is clearly shown, *Raytheon Co. v. Roper Corp.*, 724 F. 2d 951, 958 (Fed. Cir. 1983). “An invention need not be the best or the only way to accomplish a certain result, and it need only be useful to some extent and in certain applications..” *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180 (Fed. Cir. 1991); see also *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F. 3d 1364, 1366 (Fed. Cir. 1999) (the invention need only be “capable of providing some identifiable benefit”). Applicants respectfully request withdrawal of the rejection and reconsideration of the claims.

III. Rejection under 35 USC §112, first paragraph.

6. Claims 95, 96 and 117-113 were also rejected under 35 USC §112, first paragraph, on the basis that the claimed invention is not supported by either a clear, asserted utility or will establish utility for the reasons as set forth in the record. Applicants respectfully traverse this rejection.

As discussed above, the present application is supported by a specific, substantial, and credible asserted utility as well as a well-established utility. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 USC §112 and reconsideration of the claims.

IV. Rejection under 35 USC §112, second paragraph

7. Claims 95, 96 and 117-123 were rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection.

Claims 95, 96 and 117-123 have been amended by this response to moot the foregoing rejection. Specifically, claims 95, 96 and 117-123 have been amended to delete the term “5HT3E”.

8. Claims 95, 96 and 117-123 were rejected under 35 U.S.C. §112, second paragraph, as being vague and ambiguous for recitation of “fragment thereof”. Applicants have amended claims 95 and 96 to moot this rejection. Applicants respectfully request that the rejection be withdrawn and the claims reconsidered.

9. Claim 96 was rejected under 35 U.S.C. §112, second paragraph, for recitation of the term “unique”. Applicants have amended claim 96 to moot this rejection. Applicants respectfully request that the rejection be withdrawn and the claims reconsidered.

It is respectfully submitted that the amendments to claims 95, 96 and 117-123 have been made to advance the prosecution of the pending application. Applicants reserve their right to file continuing applications with regard to any deleted subject matter.

Conclusion

10. Applicants believe the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned to clarify any unresolved issues raised by this response.

Respectfully submitted,

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